

PATENT  
Customer No. 22,852  
Attorney Docket No. 07579.0015-01000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Graham Edmund KELLY et al. )  
) Group Art Unit: 1623  
Serial No.: 10/600,004 )  
)  
Filed: June 18, 2003 ) Examiner: Not Yet Assigned  
)  
For: CARDIOVASCULAR AND BONE )  
TREATMENT USING ISOFLAVONES )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**NOTICE REGARDING RELATED LITIGATION**

Applicants hereby notify the U.S. Patent and Trademark Office that a patent possibly related to the present application is involved in litigation. The present application, U.S. Serial No. 10/600,004, filed June 18, 2003, is a continuation of U.S. application Serial No. 09/914,035, filed as PCT/AU00/00384 on April 27, 2000, which entered the national stage on December 10, 2001. The patent that is involved in litigation is U.S. Patent No. 6,642,212 B1 ("the '212 patent"), issued from U.S. application Serial No. 09/421,069 on November 4, 2003, and was originally filed on October 19, 1999, as a continuation of U.S. application Serial No. 08/910,837, filed August 13, 1997, now U.S. Patent No. 6,562,380 B1. As is clear from the above, the present application and the patent in suit do not share a common specification or overlapping claims to priority although they do relate to isoflavones and are all assigned to Novogen Pty. Ltd. Nevertheless, to avoid even the appearance of impropriety, Applicants submit this notice in the event that the disclosures in the respective specifications would ever be considered related.

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**STATUS OF RELATED LITIGATION**

On November 4, 2003, Solae, L.L.C. ("Solae") filed a Complaint alleging that Archer Daniels Midland Company ("ADM") and Amerifit Nutrition, Inc. ("Amerifit") infringe at least one claim of the '212 patent. The case, Civil Case No. 4:03-CV-01595 RWS, was filed in U.S. District Court for the Eastern District of Missouri. The undersigned has been informed that Solae is the exclusive licensee of the '212 patent for products containing soy-derived isoflavones.

On November 21, 2003, ADM and Amerifit filed Defendants' Joint Motion to Consolidate. In their motion, Defendants requested consolidation of the Solae litigation described above, with a separate Solae litigation filed on June 2, 2003, also in the U.S. District Court for the Eastern District of Missouri, Civil Case No. 03-CV-732. The earlier case contends that the Defendants products infringe Solae's rights in U.S. Patent Nos. 5,990,291 (Reexamination Certificate 5,990,291 C1) ("the '291 patent")<sup>1</sup> and 6,562,380 ("the '380 patent"); the later case contends that the Defendants products infringe Solae's rights in the '212 patent, a continuation of the '380 patent. On September 11, 2003, the Applicants submitted a Notice Regarding Related Litigation to the Office in reference to the earlier litigation.

**REMARKS**

Further to this Notice Regarding Related Litigation, the Applicants submit a copy of the Complaint and a copy of the docket for Civil Case No. 4:03-CV-01595 RWS, current as of December 4, 2003.

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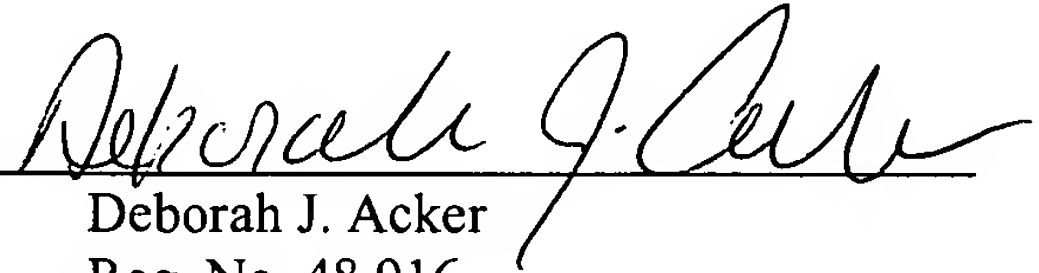
<sup>1</sup> The '291 patent is entitled "Recovery of Isoflavones from Soy Molasses," names Doyle Waggle and Barbara Bryan as inventors and is assigned on its face to Protein Technologies International.

If there are any fees due with the filing of this Notice not already accounted for, please charge the fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: December 22, 2003

By:   
Deborah J. Acker  
Reg. No. 48,916

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**FILED**

**NOV - 4 2003**

**U. S. DISTRICT COURT  
EASTERN DISTRICT OF MO  
ST. LOUIS**

**UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION**

.....  
SOLAE, LLC,

Plaintiff,

vs.

CIVIL ACTION No.:

ARCHER DANIELS MIDLAND  
COMPANY

and

AMERIFIT NUTRITION, INC.

Defendants.

SERVE DEFENDANTS AT:

(for Archer Daniels Midland Co.)  
C T CORPORATION SYSTEM  
120 South Central Avenue  
Clayton, Missouri 63105

and

(for Amerifit Nutrition, Inc.)  
CORPORATION SERVICE COMPANY  
50 Weston Street  
Hartford, Connecticut 06120  
.....)

**4:03 CV 01595 DDN**

**JURY TRIAL DEMANDED**

**COMPLAINT**

Plaintiff Solae, LLC ("Solae" or "Plaintiff"), by its attorneys, for its Complaint against Archer Daniels Midland Company and Amerifit Nutrition, Inc. ("Defendants"), alleges and avers as follows:

## **JURISDICTION AND VENUE**

1. This is an action for patent infringement arising under Title 35 of the United States Code, Chapter 28, Section 271 and Chapter 29, Section 281, *et seq.*
2. Upon information and belief, Defendants have committed infringing acts in this district and are subject to personal jurisdiction in this district.
3. Jurisdiction is conferred on this Court pursuant to 28 U.S.C. §§ 1331, 1332 and/or 1338(a).
4. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(a), (b), (c), 28 U.S.C. § 1400(b), and E.D.Mo. L.R. 2.07(B)(3) and (4).

## **THE PARTIES**

5. Plaintiff Solae, LLC (“Solae” or “Plaintiff”) is a Delaware limited liability corporation, having a principal place of business in St. Louis, Missouri.
6. Upon information and belief, defendant Archer Daniels Midland Company (“ADM”) is a corporation organized under the law of Delaware, having its principal place of business at 4666 Faries Parkway, Decatur, Illinois 62526.
7. Upon information and belief, defendant Amerifit Nutrition, Inc. (“Amerifit”) is a corporation organized under the law of Delaware, having its principal place of business at 166 Highland Park Drive, Bloomfield, Connecticut 06002.

## **BACKGROUND**

8. St. Louis-based Solae is a leader in the research, manufacturing and marketing of high-quality, soy-based ingredients and ingredient systems.
9. There are three principal classes of phyto-oestrogens: isoflavones, lignans, and coumestans.
10. Isoflavones are bioactive chemicals found naturally in plants. Soy isoflavones exist in three main families: genistein, daidzein and glycitein. Four chemical forms of isoflavones known as aglucones, glycosides, malonyl conjugates, and acetyl conjugates are found within each family. Soybeans are the major food source of the naturally-occurring isoflavones genistein and daidzein.
11. In the production of commercial products such as soy protein concentrates, the focus has been to remove soy isoflavone compounds since they are associated with the bitter flavor of soybeans. In a conventional process for the production of a soy protein concentrate, extracted material containing soy isoflavones, is typically discarded. As a result, the extract from a conventional process is an inexpensive and desirable source of soy isoflavones.
12. Recent clinical research suggests that isoflavones contained in vegetable protein materials such as soybeans, are bioactive compounds that may provide various health benefits, including the reduction of cardiovascular risk factors, the amelioration of conditions caused by reduced levels of endogenous estrogen in women (*e.g.*,

menopause or premenstrual syndrome), and the inhibition of certain human cancer cells (e.g., breast and prostate cancer cells).

13. U.S. Patent No. 6,642,212, issued November 4, 2003 (copy attached as Exhibit 1) (“the ‘212 patent”) entitled “Health Supplements Containing Phyto-Oestrogens, Analogues Or Metabolites Thereof,” names Graham Kelly as inventor and lists on its face Novogen Research Pty. Limited (New South Wales, Australia) as assignee.
14. Solae is the sole and exclusive licensee of the ‘212 patent for products containing soy-derived isoflavones. Solae was formerly known as Protein Technologies International, Inc. (“PTI”). On or about March 28, 2003, PTI was renamed and reincorporated as Solae.
15. Upon information and belief, ADM manufactures and markets a product that infringes at least one claim of the ‘212 patent, which product is known as Novasoy® (“Novasoy”) and is a powdered compound extracted from soybeans containing naturally-occurring isoflavones.
16. Upon information and belief, ADM’s Novasoy contains at least the soy isoflavones daidzein, genistein, and glycitein, their glycosides, and acetyl and malonyl esters.
17. Upon information and belief, ADM’s Novasoy isoflavone material is marketed and sold by ADM in this district and throughout the United States.
18. Upon information and belief, ADM’s Novasoy isoflavone material is marketed and sold by ADM to manufacturers for incorporation into health and/or dietary

supplements that infringe at least one claim of the '212 patent and are marketed and sold in this district and throughout the United States.

19. Upon information and belief, Amerifit manufactures and markets a product that infringes at least one claim of the '212 patent, which product is known as Estroven<sup>®</sup> ("Estroven") and is a health supplement containing Novasoy isoflavone material provided by ADM.
20. Upon information and belief, Amerifit's Estroven contains at least the soy isoflavones daidzein, genistein, and glycitein, their glycosides, and acetyl and malonyl esters.
21. Upon information and belief, Amerifit's Estroven is marketed and sold by Amerifit in this district and throughout the United States for alleviating symptoms associated with menopause.

### **FIRST CAUSE OF ACTION**

### **PATENT INFRINGEMENT**

22. Solae here repeats and incorporates by reference all the allegations of paragraphs 1 through 21 above.
23. Upon information and belief, ADM has directly and/or contributorily infringed at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.



24. Upon information and belief, ADM has knowingly induced others to infringe at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Novasoy. ADM will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
25. Upon information and belief, Amerifit has directly and contributorily infringed at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.
26. Upon information and belief, Amerifit has knowingly induced others to infringe at least one claim of the '212 patent in connection with making, using, offering to sell, selling, and/or importation of Estroven. Amerifit will continue such infringing activities, to the irreparable injury of Solae, unless enjoined by the Court.

### **REQUEST FOR RELIEF**

WHEREFORE, Solae prays that this Court enter judgment in its favor against the Defendants and grant the following relief:

- A. Permanently enjoin Defendants, their agents, successors and assigns and all persons acting on their behalf or within their control, from making, using, selling, or offering to sell, importing or otherwise engaging in acts of infringement of the '212 patent;
- B. Award Plaintiff damages caused by Defendants' patent infringement as determined by the jury in this action;

- C. Enter an order declaring this an exceptional case and awarding Plaintiff interest, costs and disbursements in this action, including reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and
- D. Award Plaintiff such further relief as the Court may deem just and proper.

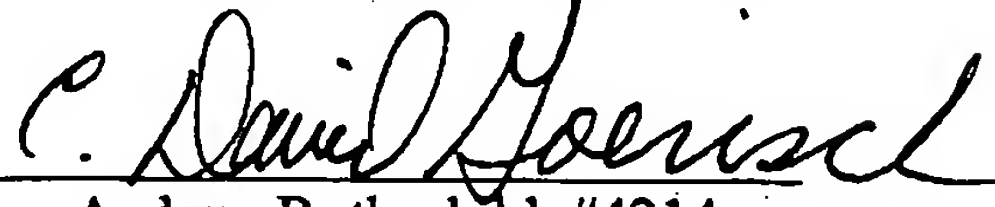
**DEMAND FOR A JURY TRIAL**

Plaintiff hereby demands trial by jury of all issues so triable in this action.

Dated: November 4, 2003.

Respectfully submitted,

**LEWIS, RICE & FINGERSH, L.C.**

By:   
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